MEETING MINUTES
OF THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES
MEDICARE COVERAGE ADVISORY COMMITTEE

September 9, 2003

Holiday Inn Inner Harbor
Lombard and Howard Street
Baltimore, Maryland

Medicare Coverage Advisory Committee

September 25, 2002

Attendees

Ronald M. Davis, M.D.
Chairperson

Barbara J. McNeil, M.D., Ph.D.
Vice-Chairperson

Michelle Atkinson
Executive Secretary

Voting Members
Wade M. Aubry, M.D.
Robert H. Brook, M.D., Sc.D.
Anne B. Curtis, M.D.
Susan Bartlett Foote, J.D., M.A.
Steve N. Goodman, M.D., M.H.S., Ph.D.
Karl A. Matuszewski, M.S., Pharm.D.
Margaret A. Piper, Ph.D., M.P.H.
Rita F. Redberg, M.D., M.Sc.
Paul J. Wallace, M.D.

CMS Liaison
Steve Phurrough, M.D., M.P.A..

Consumer Representative
Linda A. Bergthold, Ph.D.

Industry Representative
G. Gregory Raab, Ph.D.

Guest Panelists
Alan M. Garber, M.D., Ph.D.
Oliver D. Schein, M.D., M.P.H.

Tuesday, September 9, 2003, 8:07 a.m.

The Medicare Coverage Advisory Committee met on September 9, 2003, to discuss and make recommendations concerning the quality of the evidence and related issues for the use of ocular photodynamic therapy with verteporfin in routine clinical use in the population of Medicare beneficiaries who have age-related macular degeneration and occult with no classic choroidal neovascularization.

The meeting began with the introduction of the Committee, a reading of the conflict of interest statement, and a charge to the committee by the Chair.

CMS Presentation of Request and Voting/Discussion Questions. CMS representatives presented the panel with information on age-related macular degeneration in the Medicare population, a history of Medicare coverage of verteporfin, review of MCAC voting questions and discussion questions, a presentation by Dr. Charles P. Wilkinson, and a CMS review of evidence and data analysis.

Requestor's Presentation. Representatives from Novartis and QLT presented the panel with an overview of what macular degeneration is, how it can lead to a decrease in vision, and ultimately to blindness in seniors. They explained various test and trial procedures and results from the TAP and VIP trials, and responded to the points raised in the CMS presentation. Representatives from the American Society of Retinal Specialists, the American Academy of Ophthalmology, and the American Council for the Blind addressed the panel, supporting national coverage for the requested treatment. Finally, a Medicare recipient related her personal experiences with macular degeneration, and her limited financial ability to continue with therapy, and urged the panel to recommend coverage for verteporfin.

Scheduled Public Comments. Thirteen scheduled speakers addressed the panel. Representatives from Genaera and Genentech informed the panel of studies currently underway addressing possible treatment of macular degeneration that is being sponsored by their companies. Representatives of the Gray Panthers, the Seniors Coalition, the Baltimore Office of the NAACP, the American Association of People with Disabilities, the League of United Latin American Citizens, Lighthouse International, and Prevent Blindness America spoke to the panel, all encouraging CMS to adopt national coverage for verteporfin therapy for occult with no classic neovascularization. Three Medicare beneficiaries and one other individual patient, all of whom had received or were receiving verteporfin therapy, related their personal experiences to the panel.

Open Public Comments. Five speakers addressed the panel, including the daughter of a Medicare beneficiary who has been treated with verteporfin, a representative from Advancing Independence and Modernizing Medicare and Medicaid, the spouse of a Medicare beneficiary who has been treated with verteporfin, an attorney representing Novartis and QLT, and a retired physician who has received verteporfin therapy. These speakers all urged national coverage of the treatment.

Questions to Presenters. The panel engaged in a lengthy question and answer session with representatives of the requestor and CMS.

Methodological and Clinical Reviewer Presentations. Dr. McNeil stated that most of the issues she had been interested in talking about related to analyses of the whole cohort and the subcohorts, as well as the various issues relating to confounding, what was really influencing what. She commented that she would pass on the rest of her prepared remarks in view of the discussions that had taken place between the panel and the

presenters. Dr. Aubry echoed Dr. McNeil's remarks, adding that in spite of the material presented by the requestors, specialty societies and Medicare recipients, the panel should focus on the evaluation of evidence in reaching their conclusions and answering the questions presented to them.

Open Panel Discussion. Dr. McNeil moved that the voting panel delay voting to receive more information from the requestors about the new data presented to the panel today, and a response from CMS, and that the panel be given an opportunity to reconvene relatively rapidly to make their judgment on the voting questions one and two. The motion was seconded by Dr. Goodman. Following discussion, the motion was defeated, eight votes against and two votes for.

Final Remarks and Vote.

The panel voted on the following question:

Is there adequate evidence to draw conclusions about the net health benefits, that is, whether or not the risks and benefits of treatment outweigh the risks and benefits of nontreatment of ocular photodynamic therapy with verteporfin in routine clinical use in the population of Medicare beneficiaries who have age-related macular degeneration and occult with no classic choroidal neovascularization?

The results of the vote were eight yes, one no, and one abstention.

The panel then voted on the following question:

Does the evidence demonstrate that OTP with verteporfin treatment improves net health outcomes in treating age-related macular degeneration in occult with no classic neovascularization?

The results of the vote were eight yes, one no, and one abstention.

The panel then considered the following question:

What is the size of the benefit in patients receiving the treatment?

A motion was made by Dr. Curtis and seconded by Dr. Aubry that the panel categorize this therapy as more effective. At the suggestion of the Chair, it was agreed that the panelists would be polled as to the size of the benefit. The results of the poll were seven in favor of more effective, one in favor of substantially more effective, and two abstentions.

Dr. Phurrough informed the panel that it would not be necessary to formally consider the discussion questions, and that CMS would take the entire record into consideration in forming the ultimate coverage decision.

Adjournment. The meeting adjourned at 3:30 p.m.

I certify that I attended the meeting of the Executive Committee on September 9, 2003, and that these minutes accurately reflect what transpired.

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Michelle Atkinson
Executive Secretary, MCAC, CMS

I approve the minutes of this meeting as recorded in this summary.

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Ronald M. Davis, M.D.
Chairperson